

REMARKS

Applicants' agent wishes to thank the Examiner for the careful consideration given this case. Applicants thank the Examiner for the telephonic interview of June 1, 2004, during which the form of the present claims was discussed. Claims 1, 5, 18, 20, and newly-introduced Claim 46 are pending in this case. Herein, Claims 1, 5, 18, and 20 are amended. Claims 2-4, 6-17, 21-45 are hereby cancelled.

This response addresses those issues raised in the Office Action dated December 18, 2003. It is believed that the present amendments and following remarks render all pending claims allowable. Reconsideration of the claims as presently amended is respectfully requested.

The Examiner objects to the specification as it contained embedded hyperlinks. Applicants have amended the specification to remove the offending hyperlinks, thus rendering the objection moot.

The Examiner objects to Claims 1-7, 20, and 40-43 as containing non-elected subject matter. Claims 2-4, 6-7, and 41-43 are cancelled. Applicants confirm election of Group I and also election of SEQ ID NO:3 for further examination. Provisional election of mutation T at base number 4121 of SEQ ID NO:3 was also submitted, but traversed in the response in the response dated September 19, 2003. While the Examiner has made the restriction requirement final in the present Office Action, Applicants again request relaxation of certain aspects of the restriction requirement. Applicants have narrowed the focus of the presently-pending claims to SEQ ID NO: 3 and the variations in SEQ ID NO:3 that are listed in presently-amended Claim 1. Applicants again respectfully submit that the Examiner is permitted to evaluate these sequences under MPEP § 806.04, which reads "it has been determined that normally ten sequences constitute a

reasonable number for examination purposes.” It is respectfully submitted that the sequences for which Applicants are requesting examination clearly fall within the scope of permissible evaluation by the Examiner. In addition, the Examiner indicated that she would consider these variations during the telephonic interview of June 1, 2004. Reconsideration of the finality of the restriction requirement is earnestly and respectfully requested.

The Examiner rejects Claims 18-19 under 35 U.S.C. § 101 as she alleges that they are not directed to statutory subject material as they encompass human subjects. Claim 19 has been incorporated into presently-amended Claim 18. Claim 18 now recites (in relevant part) “An expression system [...] wherein said expression system comprises a recombinant host cell transformed or transfected with said DNA sequence.” (Emphasis added.) Applicants intend “expression system” to be interpreted as it is commonly used by those skilled in the art, *i.e.* cellular expression systems in which host cells are transformed or transfected with the DNA sequence of interest. Examples of such host cells are bacterial cells, HEK-293, HEK-293T, COS-7 cells, and CHO cells. One of ordinary skill in the art would be aware of many examples of such host cells that are suitable for use as an expression system. Reconsideration and withdrawal of the rejection under § 101 are respectfully requested.

The Examiner rejects Claims 1-7, 18-19, and 40-43 under 35 U.S.C. § 112, ¶1 as containing subject material that is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors at the time of application had possession of the claimed invention. Specifically, the Examiner notes that the claims recite SEQ ID NO:3 and “contiguous portions thereof.” The Examiner goes on to state that the contiguous sequence of SEQ ID NO:3 encompasses a large group of nucleic acid sequences that may reside outside

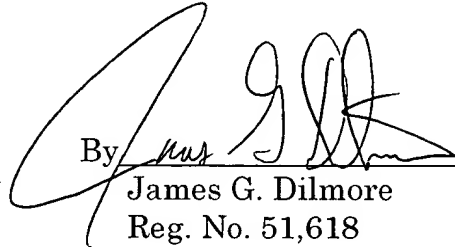
of SEQ ID NO:3. Claims 2-4, 6-7, 19, and 42 are cancelled. Applicants wish to clarify their use of the language found in presently pending Claim 1. Applicants use the term “contiguous” as language in the present claims to mean “connecting without a break.” (American Heritage Dictionary of the English Language, Fourth Edition, 2000.) As such, “contiguous portions thereof” is meant to refer to only continuous fragments of SEQ ID NO:3 – not fragments outside of or adjacent to SEQ ID NO:3. It is respectfully submitted that this clarification renders the claims definite and well described under § 112, ¶1. Reconsideration and withdrawal of the present rejection are respectfully requested.

The Examiner rejects Claims 18 and 19 under 35 U.S.C. § 112, ¶1. Claim 19 is now cancelled. As explained above, it is respectfully submitted that presently-amended Claim 18 is limited to expression systems comprising a host cell only, thus rendering the present rejection moot. Reconsideration and withdrawal of the present rejection are respectfully requested.

In view of the foregoing remarks, it is believed that the present application is in condition for final allowance and notice to such effect is respectfully requested.

If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Dated: June 18, 2004

By  _____
James G. Dilmore
Reg. No. 51,618

Frederick H. Colen
Reg. No. 28,061

REED SMITH LLP
P.O. Box 488
Pittsburgh, PA 15230-0488
(412) 288-3813

Agent and Attorney for Applicants